REMARKS

Claims 1, 4, and 42-44 are pending. These claims were rejected under 35 U.S.C. § 112, first paragraph. Applicants address this rejection as follows.

Claim Amendments

Applicants have added new claims 45-50. Claims 45-49 find support, for example, at page 4, line 15, to page 5, line 6, and claim 50 finds support, for example, in original claim 1 and at page 5, lines 7-23, of the English language translation of the specification as filed. In addition, Applicants have amended claim 1 to refer to the glycostructure as an "N-linked" glycostructure. This amendment finds support, for example, at page 4, lines 15 to 24, of the English language specification. No new matter has been added by these amendments.

In addition, as claim 50 is directed to the invention claimed in original claim 1, which is part of the restriction group pursued in the present application, Applicants submit that claim 50 also falls into this restriction group.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 4, and 42-44 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Office asserts (page 3, page 4):

> The specification ... is remiss of information detailing what defines tumor-specific glycostructure and how one of ordinary skill in the art could identify said structure. There is insufficient guidance regarding the section of said protein that is to have this specific structure. It is not clear how one of ordinary skill in the art could definitively recognize whether or not they were also in possession of Applicants' claimed invention.

Applicants respectfully disagree.

The standard for adequate written description is whether the description clearly allows persons of ordinary skill in the art to recognize that one has invented what is claimed. On this point, M.P.E.P. § 2163.02 (Eighth Edition, Revision 2, May 2004) states:

> [A]n objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed."

In applying this standard, the Federal Circuit has held:

> It is not required that the application describe the claim limitations in greater detail than the invention warrants. The description must be sufficiently clear that persons of skill in the art will recognize that the applicant made the invention having those limitations. *Martin v. Mayer*, 823 F.2d 500, 3 U.S.P.Q.2d 1333 (Fed. Cir. 1987).

And:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

Applicants' specification clearly meets this standard for the claims 1, 4, and 42-44, as well as for new claims 45-50. The structure of human CD55/DAF was well known in the art at the time the present application was filed (see, e.g., U.S. Patent No. 5,763,224, copy enclosed). Further, as taught, for example, at page 5, lines 12-18, of the specification, Applicants determined that a CD55 protein with a tumor-specific N-linked glycostructure, as presently claimed, has a molecular weight of about 82 kD. Applicants submit that, based on molecular weight, one skilled in the art would recognize that this 82 kDa isoform of CD55 is different from other DAF/CD55 isoforms expressed by non-tumor tissues, e.g., the 70 kDa DAF/CD55 protein described by Medof et al. (J. Exp. Med. 160:1558-1578, 1984; previously cited by the Office).

Moreover, antibodies that recognize the CD55 primary structure, and thus recognize both wild-type and tumor-specific forms of CD55, were available in the art at the time the present application was filed (see e.g., Hara et al., Immunol. Lett. 37:145-152, 1993; and Coyne et al., J. Immunology 149:2906-2913, 1992, at page 2907, in the first column; "Coyne;" copies enclosed). As described in Applicants' specification, e.g., at page 20, lines 10-19, page 28, lines 12-22, and in Figure 1A, of the English language specification, one skilled in the art can readily determine the molecular weight of a polypeptide using an antibody and standard techniques, such as Western blotting. Consequently, based on the description provided in Applicants' specification, one skilled in the art can readily distinguish CD55 lacking a tumor-specific N-linked glycostructure

from one containing such a glycostructure.

Furthermore, in response to the Office's assertion that "there is insufficient guidance regarding the section of said protein that is to have this specific structure" Applicants note that claim 1 and its dependent claims are directed to a glycoprotein having the human amino acid primary structure of CD55 and a tumor specific N-linked glycostructure. These claims are not directed to a particular section of the CD55 protein and, therefore, Applicants submit that this basis of rejection does not apply to claim 1 and its dependent claims.

New claim 50 is directed to a glycoprotein that includes a section of CD55 that contains a tumor-specific N-linked glycostructure. As shown in Figure 7 of Coyne, CD55/DAF only contains one N-linked glycosylation site. Thus, given that the sequence of CD55 and the location of its N-linked glycosylation site were publicly known at the time the application was filed, Applicants submit that one skilled in the art would recognize which section of CD55 contains a tumor-specific N-linked glycostructure.

Finally, Applicants note that that the specification teaches, for example, at page 5, lines 12-18, that the tumor-specific isoform of CD55 can be obtained from deposited human adenocarcinoma cell line 23132. Thus, Applicants describe a publicly available cell line which expresses the glycoprotein encompassed by the present claims.

In sum, Applicants teach, in their specification, the molecular weight of the isoform of CD55 that includes the tumor-specific glycostructure, that the tumor-specific glycostructure is N-linked, and that this isoform is a glycoprotein expressed by deposited cell line 23132. Clearly Applicants' specification allows one skilled in the art to recognize that one has invented what is claimed. The 35 U.S.C. § 112, first paragraph rejection of claims 1, 4, and 42-44 should be withdrawn. For all the above reasons, Applicants also submit that new claims 45-50 are free of this basis for rejection.

CONCLUSION

Applicants submit that the application is now in condition for allowance and this action is hereby respectfully requested.

Enclosed are a Petition to extend the period for replying to the final Office Action for three months, to and including August 26, 2004, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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